REMARKS

STATUS OF CLAIMS

Claims 1, 3-13 and 15-30 are pending in the application. Claims 2 and 14 are cancelled. Claims 15 and 19-29 have been withdrawn pursuant to a restriction requirement. New Claim 30 has been added. Claim 1 has been amended to describe additional features of the invention and add the description from Claim 2; support for these change may be found in Claim 2 and the specification, for example, page 5, paragraph 26; page 6, paragraph 29; and page 9, paragraph 37. Claim 2 has been cancelled as included in amended Claim 1. Claim 10 has been amended to correct a minor typographical error. New Claim 30 has been added; support for this claim may be found in the specification, for example, page 6, paragraph 30. No new matter has been added by any of these changes. Thus, Claims 1, 3-13 and 15-30 are presented for examination.

INFORMATION DISCLOSURE STATEMENTS

Two IDS's have previously been submitted in this case (January, 2004 and March, 2005). The attorney records do not reflect the return of initialed and dated copies of these IDS documents from the Examiner indicating that the Examiner has reviewed and considered the listed references. It is respectfully requested that the Examiner review and consider the listed references and provide the dated and initialed copies to Applicants' attorney.

PROVISIONAL DOUBLE PATENTING REJECTION

In the Office Action, the Examiner has rejected Claims 1-13 and 16-18 on the ground of non-statutory obviousness-type double patenting on the basis of claims 1-23 of U.S. Patent Application Serial No. 10/894,400; claims 1 and 4-23 of U.S. Patent Application Serial No. 10/632,008; and claims 1-24 U.S. Patent Application Serial No. 10/409,358 each individually.

In response to these provisional double patenting rejections, Applicants, through their attorney, respectfully traverse the non-statutory obviousness-type double patenting rejection and its accompanying remarks. Applicants also respectfully state that the instant double patenting rejections will be addressed (1) if and when the "provisional" non-statutory obviousness-type double patenting rejection in each application is the only rejection remaining in that application; and/or (2) if and when the cited applications are issued as patents. See MPEP 804 I B:

> *If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection* and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Thus, since the co-pending applications have not issued as patents and the claims may be amended in the future, Applicants respectfully exercise their right to address the provisional rejections at a future date, particularly if and when the cited applications are issued as patents.

REJECTION UNDER 35 U.S.C. § 102(b)

The Examiner rejects Claims 1 and 4-9 as being anticipated under 35 U.S.C. § 102(b) by Phan et al. (U.S. Patent No. 5,674,242) ("PHAN"). This rejection is respectfully traversed. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

PHAN teaches an endoprosthetic device for insertion at a vascular site is described. The device is composed of a structural member carrying a polymer member having an embedded therapeutic compound. The polymer member is formed of a shape-memory polymer for expansion upon exposure to a selected stimulus. The structural member is designed for coexpansion with the polymer member when the device is exposed to the stimulus. PHAN teaches the use of UV light to cause crosslinking in a mixture of monomers comprising methyl methacrylate, polyethyleneglycol methacrylate, butylemethacrylate in a 2:1.5:1 ratio with a crosslinker such as hexanedioldimethyacrylate and a thermal or UV initiator such as benzoin methyl ether or azobisisobutylnitrile (see col. 6, lines 21-64). Example 2 of PHAN describes the extrusion of a blend of polyocetenylene, polyethylene glycol and triallyl isocyanurate (crosslinking agent) with the extruded product then being crosslinked by exposure to irradiation in the form of a 2.5 Mrad electron beam. In comparison to the present invention, neither of these polymer systems is found in the Claims of the current invention. Not only does PHAN not teach the invention as currently claimed, PHAN emphasizes the crosslinking of selected polymers and even adds crosslinking agents that will drive the reaction to effect such crosslinking with the

effect of increasing molecular weight. Importantly, the medical device of the current invention comprises a polymeric release region comprising a selected polymer, wherein the selected polymer comprises radiation sensitive groups so that when treated with an effective radiation dose of at laest 100,000 rads, the effect will be to (i) reduce the molecular weight of the polymer and (ii) substantially increase the cumulative release of said therapeutic agent subsequent to administration to a patient, particularly in an amount of at least 10%. In contrast to the present invention, there is no mention in PHAN of (a) how to control the release of therapeutic agents in the face of PHAN's emphasis on driving the reaction to crosslinking or (b) the selection of certain types of polymers (as currently claimed in the present invention) that would be useful to form polymeric release regions that would increase the cumulative release of said therapeutic agent. Thus, each and every element of the invention is not disclosed and the rejection under 35 U.S.C. § 102(b) should be withdrawn.

REJECTION UNDER 35 U.S.C. §103(a)

The Examiner has rejected Claims 10-14 and 16-18 under 35 U.S.C. §103(a) on the basis of PHAN in view of Pinchuk (U.S. Application Publication No. 2002/0107330) ("PINCHUK") and further view of Furst (U.S. Application Publication No. 2002/0099438) ("FURST"). This rejection is respectfully traversed. The Examiner has not met her burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) ***must teach or suggest all the claimed features***. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success ***must both be found in the prior art, not in applicant's disclosure***. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The relevance of PHAN has been discussed above, especially with regard to the point that PHAN emphasizes the crosslinking of selected polymers and even adds crosslinking agents that will drive the reaction to effect such crosslinking. PINCHUK describes a composition for delivery of a therapeutic agent wherein the composition comprises: (a) a biocompatible block copolymer comprising one or more elastomeric blocks and one or more thermoplastic blocks and

(b) a therapeutic agent, wherein the block copolymer is loaded with the therapeutic agent. The elastomeric blocks are preferably polyolefin blocks, and the thermoplastic blocks are preferably selected from vinyl aromatic blocks and methacrylate blocks. The Examiner's attempt to combine PINCHUK with PHAN is not supportable. PHAN requires the use of shape-memory polymers in a device that has at least two components (a structural member and a polymer member) that can co-expand with each other. This is different than PINCHUK which describes a composition comprising specific blocks of selected polymer types to achieve a desired combination of hardness and elasticity. There is no teaching or suggestion that the block copolymer compositions of PINCHUK could be used in PHAN or that the shape-memory polymers of PHAN could be used in PINCHUK Most importantly any attempted combination of PHAN and PINCHUK would also fail since PINCHUK does not teach or suggest the use of any radiation treatment for any purpose at all. In fact, the words "radiation," and "irradiate" do not even appear in the text of PINCHUK. Additionally, PINCHUK describes therapeutic agents being released over time, while the present invention claims an increase in the release rate based on the treatment of the polymeric release region with radiation. Thus, one skilled in the art would not look to PINCHUK to combine with PHAN.

The Examiner supplements her rejection under 35 U.S.C. §103(a) with the citation of FURST; likewise this rejection cannot be sustained. FURST describes a stent treated with gamma, beta and/or e-beam radiation to reduce the vascular narrowing of a stented section (paragraph 21). Exposure to crosslinking of a polymeric coating on a stent (but not the stent itself) is also described (paragraph 39). While FURST indicates that the exposure to radiation alters the release of one or more vascular active agents or biological agents into the body passageway and that the release is controlled by the amount of crosslinking (paragraph 74), the amount of radiation used in FURST is less than 2000 rads, which is orders of magnitude below the minimum amount of 100,000 rads claimed in the present invention. It should also be noted that the 2000 rads is the upper limit of FURST and FURST even teaches away from the current invention by suggesting that lower amounts of radiation should be used (paragraph 39, last sentence).

The Examiner has rejected Claims 2-3 on the basis of PHAN in view of Cruise (U.S. Patent No. 6,537,569) ("CRUISE"). This rejection is traversed for the reasons described above for PHAN. Additionally, the relevance of CRUISE and the combination of CRUISE with PHAN

are not supportable. CRUISE teaches the use of hydrogels. The description of these hydrogels and the synthesis of biodegradable, radiation-crosslinked hydrogels from polymeric starting materials in CRUISE is not shown to be substitutable for the polymers in PHAN which require shape-memory properties. CRUISE also does not teach irradiating a polymer to increase the cumulative release of the therapeutic agent from the device, or to have any impact whatsoever on the release kinetics of a therapeutic agent from a polymer.

Given the above remarks and the amendments to the claims, it is believed that the Examiner's rejection under 35 U.S.C § 103(a) has been obviated and withdrawal of this rejection is requested.

CONCLUSION

Applicants submit that Claims 1, 3-13, 16-18 and 30 are in condition for allowance. Reconsideration of the case and a Notice of Allowability are requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

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Respectfully submitted,

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